

MAY2016-07-01 - Registration Eligibility Criteria Data Dictionary

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Document Summary

Property	Value
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MAY2016-07-01 - Registration Eligibility Criteria: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	SUBJECT	Participant Identifier		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	FOLDERINSTAN CENAME	Dataset Folder Name		"Baseline"="Baseline"
01. Principal	MAXUPDATED	Last Updated		SAS Date
01. Principal	MINCREATED	Created Time		SAS Date
01. Principal	PAGEREPEATNU MBER	Page Repeat Number		Numeric
01. Principal	PROJECT	Protocol		"MAY2016-07-01"="MAY2016-07-01"
01. Principal	RAVEID	Rave ID		Numeric
01. Principal	RECORDPOSITIO N	Record Position		Numeric
01. Principal	SITE	Site		"Cleveland Clinic Foundation"="Cleveland Clinic Foundation" "Huntsman Cancer Institute/University of Utah"="Huntsman Cancer Institute/University of Utah" "M D Anderson Cancer Center"="M D Anderson Cancer Center" "Mayo Clinic in Arizona"="Mayo Clinic in Arizona" "Mayo Clinic"="Mayo Clinic" "University of Michigan Comprehensive Cancer Center"="University of Michigan Comprehensive Cancer Center" "University of Pittsburgh Cancer Institute (UPCI)"="University of Pittsburgh Cancer Institute (UPCI)" "University of Puerto Rico"="University of Puerto Rico"
01. Principal	SITENUMBER	Site Number		"AZ020"="AZ020" "MI014"="MI014" "MN026"="MN026" "OH027"="OH027" "PA015"="PA015" "PR008"="PR008" "TX035"="TX035" "UT003"="UT003"
01. Principal	TARGETDAYS	Target Days From Baseline		Numeric

Section 3: Registration Eligibility Criteria

Class	Variable	Label	Description	Format Text
01. Principal	DF1	FAP		1="Classic" 2="Attenuated"
01. Principal	DF2	Baseline Aspirin Use:		1="No Regular Use" 2="d81 mg Day"
01. Principal	DF3	Severity Of Duodenal Polyposis		1="Spigelman 2" 2="Spigelman 3"
01. Principal	DF4	APC Genetic Mutation		1="Yes" 2="No" 3="Not Known, Not Reported"
01. Principal	EXCLU001	Histologically-Confirmed High Grade Dysplasia (Hgd), Cancer, Or Polyp Burden That Is Not Quantifiable		2="No"
01. Principal	EXCLU002	Regular (2 Times Per Week) Use Of Drugs That Alter The Ph Of The GI Tract, Such As Proton Pump Inhibitors (PPI) And Antacids		2="No"
01. Principal	EXCLU003	Gastrointestinal Bleeding		2="No"
01. Principal	INCLU001	Ecog Performance Status D1		1="Yes"
01. Principal	INCLU002	Adequate Bone Marrow And Organ Function: Leukocytes (WBC) 3,000/UI (2,500/UI For African-American Participants).		1="Yes"
01. Principal	INCLU003	Adequate Bone Marrow And Organ Function: Platelet Count 100 X 10 ⁹ /L		1="Yes"
01. Principal	INCLU004	Adequate Bone Marrow And Organ Function: Hemoglobin 11.5 G/Dl		1="Yes"
01. Principal	INCLU005	Adequate Bone Marrow And Organ Function: Total Bilirubin D 1.5 X Institutional Upper Limit Of Normal UNL		1="Yes"
01. Principal	INCLU006	Adequate Bone Marrow And Organ Function: Alkaline Phosphatase D 1.5 X Institutional Upper Limit Of Normal UNL		1="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	INCLU007	Adequate Bone Marrow And Organ Function: AST/SGOT 2 X Institutional Upper Limit Of Normal UNL		1="Yes"
01. Principal	INCLU008	Adequate Bone Marrow And Organ Function: ALT/SGPT 2 X Institutional Upper Limit Of Normal UNL		1="Yes"
01. Principal	INCLU009	Adequate Bone Marrow And Organ Function: Creatinine Institutional Upper Limit Of Normal		1="Yes"
01. Principal	INCLU010	Adequate Bone Marrow And Organ Function: Urinary Test Results Within Institutional Limits Of Normal Or Deemed Not Clinically Significant		1="Yes"
01. Principal	INCLU011	Not Pregnant Or Breast Feeding		1="Yes" 3="Not Applicable"
01. Principal	INCLU011A	Spigelman 2-3		1="Yes"
01. Principal	INCLU012	Willing To Use Adequate Contraception To Avoid Pregnancy Or Impregnation Until 2 Weeks After Discontinuing Study Agent		1="Yes" 3="Not Applicable"